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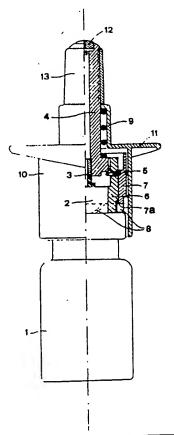
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(54) Title: MECHANICAL SELF-ACTUATED SYSTEM FOR MEDICAMENT ATOMIZING DISPENSERS

(57) Abstract

Mechanical self-actuated system for particular pharmaceutical packs the contents of which shall be administered as an atomized spray of exact small doses, said packs being either of the multi-use or the single-use type and having incorporated therein a dosing pump to be actuated manually with a given force to ensure a perfect atomization; however, patients cannot exert or measure said force exactly and thus they cause insufficient and not atomized dispensations; the system according to this invention aims to avoid this disadvantage by using a spring-loaded self-actuated head with a first manual actuation step for loading the spring (9) and a successive snap-release step by the action of a mechanical self-release (5, 6, 7) at the end of the stroke for actuating the delivery pump, said pump being therefore actuated with the exact force for an optimum atomization, said force depending only upon the exact choice of the spring (9).



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Mechanical self-actuated system for medicament atomizing dispensers.

DISCLOSURE

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In the pharmaceutical field, in order to solve some 5 particular curative problems, specific packs have been developed either for single-use or multi-use utilization, comprising a container having a pump incorporated therein and manually-actuated dispenser for administration by means of an atomized and dosed spray. Practically, said packs 10 have given satisfactory results, but lately - due to the type of medicaments to be administered, which are concerned with serious pathologies - the qualitative requirements of dispensation have become more strict and the known dispensers have shown to be not sufficiently dependable. 15 Therefore, the specialized manufacturers have been required to solve new problems, and the article of the invention aims to provide a reliable and practical solution.

The container/dispenser packs being marketed presently are based on manually-actuated mechanical systems wherein the user's depression of the slider which transfers the thrust to the pump mainly affects the quality of the dispensation. If, for example, the slider is depressed slowly, the dispensation is unsuitable, i.e. dropwise, with a not atomized jet or the like, which compromises the uniform distribution over the nose mucosa and is detrimental to the absorption of the medicament. Therefore, the problem to be solved is how to render the quality of dispensation independent of the amount and the speed of depression exerted by the user onto the slider of the control head; the article of the invention aims to solve this problem. Substantially, the control head of the present invention

constitutes the control and atomization manual system for the assembly of the medicament administering pack; the container and the pump arranged therein, with the sealed portion provided with a protruding cylindrical attachment neck, are unchanged. The proposed control assembly will be normally introduced into said neck in lieu of any other

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known assembly; however, thanks to a self-actuated and self-loaded snap system, it has the peculiarity of ensuring a perfect atomized and dosed dispensation as desired, regardless of the pressure or actuation speed on the slider. Briefly, therefore, the basic principle of the invention is based on the use of a spring-loaded selfactuated mechanical system which during the actuation stroke comprises a first spring-loading step successive automatic snap-release of the stored energy, dosing dispensing and actuates the which automatically, constantly and independently. The mechanism developed for this automatic snap-release at the end of the stroke comprises a resilient elastic element which tends, or is forced, to change its shape and position to permit the unlocking and release of the tension stored in the spring while being loaded. This resilient element can be provided with different shapes, as under described, while mantaining its detent function unchanged.

The accompanying drawings show in different scales, by way of non-limiting examples, a basic embodiment of the article of the invention, with some possible modifications tending to facilitated the realization of the system on an industrial scale and its application on the different packs being marketed. In the drawings:

- Fig. 1 is a fragmentary axial sectional view of the multidose container/dispenser assembly being concerned, with a manually-controlled and automatically snap-actuated head according to the invention;
- Fig. 2 is a fragmentary enlarged axial sectional view of the head of Fig. 1 prior to the actuating stroke and loading of the compression coil spring;
 - Fig. 3 is a view similar to Fig. 2, with the system in the position when the snap actuation for dispensation has occurred;
- Fig. 4 is a fragmentary side elevational and partly axial sectional view similar to Fig. 1, of a modified embodiment with a resilient self-release expansion-effective member, in its rest condition;

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Fig. 5 is a view similar to Fig. 4 at the end of the dispensing step effected by the snap-release of the spring as a result of the compression, through the supporting bush, of the resilient member so as to eliminate its opposing action;

Fig. 6 is a view similar to Fig. 4 of a slightly modified embodiment, i.e. comprising an outer sleeve in the form of an internal annular ridge integral with the body constituting the slider of the atomizing assembly and adapted to compress the resilient member;

Fig. 7 is a view similar to Fig. 6, with the parts in the condition at the end of the dispensing step, i.e. after the self-release of the previously-loaded spring;

Fig. 8 is a fragmentary side elevational and partly axial sectional view of an atomizing head according to the present invention, as a modification for application on single-use atomizers, the components being in the rest condition, i.e. before the spring is loaded;

Fig. 9 is a view similar to Fig. 8, the components being in the position occurring at the end of the dispensing step, i.e. after the self-release of the previously-loaded spring;

Fig. 10 is a fragmentary side elevational view of a guide bush wherein, as a detail modification, the resilient member is molded integral with said bush;

Fig. 11 is a sectional plan view on the line B-B of the Fig. 10;

Fig. 12 is a view similar to Fig. 8 of a single-use atomizing head with a modified release system based on the use of an opposing resilient member in the form of shaped slitted bush instead of a ring;

Fig. 13 is a fragmentary side sectional view of the resilient shaped bush of Fig. 12;

Fig. 14 is a plan view of Fig. 13;

Fig. 15 is a view referred to the Fig. 8 to 14, showing a further modification of the components for the self-release of the spring which causes the atomized dispensation.

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As shown clearly in Fig. 1, the container/dispenser for substantially administration endo-nasal multi-dose having inserted therein a comprises a container 1 conventional sealed pump with a protruding cylindrical neck 2 and a feeding tube 3 for the solution to be dispensed; on said cylindrical neck there can be locked any known system of control and atomization head. In the present instance and as shown, there is locked a head which is constructed as proposed by the invention, said head comprising a cylindrical tubular body 4 having the atomizing nozzle 12 on the top thereof, a supporting bush 6, an outer sleeve 7 provided with depending resilient projections 8, a compression spring 9 and, finally, a slider 10 with depression and grip radial planar extensions 11.

The operation of the head will be described hereinafter with particular reference to Figs. 2 and 3. In the rest position shown in Fig. 2, the compression spring 9, which rests on a lower shoulder of the tubular body 4, is released though having, anyway, the capability of keeping the slider 10 in the raised position. In this position the bush 6 has a resilient abutment element 5, operating in a slotted groove in "Seeger" ring fashion, in a protruding position wherein it opposes the descent of the cylindrical tubular body 4. The resilient ring 5, in this position, is 25 obliged to protrude inwardly of the sleeve 7. Therefore, by depressing the slider 10 downwards for use, at the beginning of the stroke thereof, thanks to the preestablished clearance indicated at "A", the spring 9 is depressed and is loaded, while the other parts keep still due to the locking action of the ring 5. However, as soon as the clearance "A" is eliminated, the inside planar portion of the slider 10, which is of cup-shape, abuts against the circular top end of the sleeve 7 and moves it downwards. At a suitable position, said sleeve 7 is formed with a circular enlargement which, as seen in Fig. 3, upon reaching the level of the resilient ring 5, permits the latter to expand. As a result, the inward protruding portion of the ring is retracted and the cylindrical

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tubular body 4, due to the action of the loaded spring 9, moves downwards with a strong snap action and causes the 12, said dispensation through the atomizing nozzle dispensation being always constant and independent of how the user has depressed the slider 10 of the head. Finally, it is to be noted that, in order to limit the spring's expansion and the slider's stroke upwards, according to the invention, a threaded sleeve 13 or any other means having the same effect is fitted on the end of the cylindrical tubular body 4. As a further provision for positioning the sleeve 7, the latter is provided at the bottom with an inwardly protruding rim 7a which, in detent fashion, engages a corresponding shoulder on the supporting bush 6. Once the depression action is terminated, and the slider 10 released, the system returns to its rest condition by means spring (not thrust provided by the valve represented) against the cylindrical tubular body 4 through the feeding tube 3, the return of the spring 9, which moves upward the slider 10, and the thrust provided by the resilient projections 8 to the sleeve 7.

The present system, yet preserving the basic characteristics, is liable to various modifications, as shown in the Figs. 4 to 15.

Figs. 4 and 5 show a modification wherein the resilient element 105 is normally in an expanded position and is accommodated in a circular groove made on the lower collar of the cylindrical tubular body 104. The outer sleeve 107 is provided with an upper inner edge.

As a result, when the slider 110 is depressed for use, at the beginning of its stroke, due to the pre-established clearance "A", the spring 109 is compressed and loaded, but the other parts will keep still because the resilient ring 105, acts as a detent. However, as soon as the clearance "A" is eliminated, the sleeve 107 is lowered and the bevel at its inner edge urges the resilient ring 105 radially so as to eliminate its axial detent function. Then, the cylindrical tubular body 104, urged by the loaded spring 109, will be snapped down strongly to the position

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of Fig. 5 and will cause the dispensation through the atomizing nozzle with an identical result as the one previously described.

Figs. 6 and 7 show a further detail modification wherein an annular ridge 207 molded integrally in the interior of the slider 210 substitutes for the outer sleeve 107. Said ridge 207 has the same outline as the upper inner edge of the sleeve 107 and ensure the same function thereof, with the advantage of eliminating a separate component.

According to the invention, the system can be applied, still in the field of atomizing dispensers for medicaments to be administered in endo-nasal manner, with the same advantages, to the kwown single-dose or single-use packs. Some modifications developed for this instance are shown in the Figs. 8 to 15, and these modifications, still based on

the same operating principle, will be described below. Figs. 8 and 9 show a first modification. The main body 312 of the dispenser and the cylindrical housing 310 associated therewith constitute the basic portions and enclose the tubular member 303 having at the top the atomizing nozzle and at the bottom the pumping plunger operating in the container 301 containing the dose of solution to be dispensed and which is axially slidably inserted in the tubular member 303. Externally thereof is also axially mounted the bush 306 having the task of guiding the housing 310 with respect to the container 301 with a stroke which is limited by suitable stops. Arranged between the bottom of the cup-shaped housing 310 and the closed end of the container 301 is a coil spring 309 having the function to effect, after the manual loading and as a result of the the snap-release for self-release, the dispensation of the packed substance. The self-release occurs according to the basic principle of the invention, i.e. by the action of a resilient annular member 305 accomodated in a suitable seat in the bush 306 and tending to protrude towards the inner wall 307 of the housing 310 which, however, in the rest condition and successively in

the loaded condition (Fig. 8), opposes its expansion.

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In these conditions, the resilient member 305, in this instance of flattened round section, protrudes inwardly and prevents the centering cup 304 for the spring 309 mounted on the container 301, from advancing and effecting the dispensing stroke. In the use, the single-use pack is grasped as usual, with the thumb against the bottom of the housing 310. When depressed, the latter is moved as shown by the arrow and the spring 309 is loaded until (Fig. 9) the member 305 may expand into the larger diameter chamber of the housing inner wall 307 and, therefore, ceases protruding inwardly, thus releasing immediately the components 305 and 304 which, urged by the loade spring 309, will be advanced suddenly and will cause an energetic dispensation and a perfect atomization.

A number of changes may be made to the above, some of which are shown by way of illustration in the Figs. 10 to 15.

Figs. 10 and 11 show a modification wherein the annular resilient member is molded integrally with the guiding sleeve. In this instance, the bush 406, similar to the original bush indicated at 6 in the Figs. 1,2,3 and at 306 in the Figs. 8 and 9, at a suitable level has two slits to form integrally, in the thickness of the wall, two resilient ring segments 405 which are provided at the respective free ends, with a suitable protrusion 400 each having the function of bearing against the sleeve 7 or the housing wall 307, or against the cylindrical tubular element 4 or the cup 304 so as to act like the resilient member or ring 5 or 305 and substitute for it.

In a successive modification, as clearly shown in Fig. 12, the bush 306 and the resilient element 305 are replaced with a slitted resilient tubular member 506 shown in the detail Figs. 13 and 14, which thanks to a shaped edge 505, in the rest condition, bears against the inner side of the slider 512. The member 506 has fitted axially slidably thereon the mouth of the housing 510 and the spring 509 bears against said housing. The operation of the self-release is simple: upon depression for use against the bottom of the housing 510 to cause it to advance along the

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cylindrical portion of the member 506, the spring 509 is loaded. On completion of this stroke, the edge 507 of the mouth of the housing 510 engages the outer shaped slitted collar 505 of the resilient member and depresses it up to a level to make it lose its abutted condition, whereupon the assembly is snapped forward and causes the finely atomized dispensation as required.

The slitted resilient tubular member 506 may be constructed of different shapes and with a larger number of sectors and slits still within the operative principle thereof.

In a further modification shown in Fig. 15, the resilient member 506 is replaced with a cylindrical sleeve 606 on the upper end of which rests a slitted annular resilient member 605 having a shaped and externally conical edge which operates similarly to the preceding modification. Also the operation is the same as that which has been described above.

As to detent and opposing member devised by the system of the invention as the basic member for effecting the snap dispensing step of the solution to be atomized, it is 20. finally to be noted that said member may be provided in many other shapes and, if desired, it may be replaced with mobile members of various kinds, such as balls or the like. As to the remainder, all as described and shown, made of material, liable to modifications and any suitable 25 improvements, still within the basic principle of the invention.

CLAIMS

1- Mechanical self-actuated system for atomizing medicaments packaged in containers dispensers of having a pump incorporated therein, which containers may 5 be indifferently of the conventional either multi-use or single-use types, said system being mounted as usual on the protruding cylindrical neck of said pump and being characterized in that it incorporates a mechanical selfactuated spring-loaded system which, during the actuation 10 stroke, comprises a first spring-loading step and a successive snap-release of the stored energy which actuates the dispensing and dosing pump automatically, constantly and independently. Said system, in the case of the multiapplications comprising an actuating dose 15 that it is formed by a central in characterized cylindrical tubular body (4) having the atomizing nozzle (12) at the top and pre-arranged for fitting on the delivery tube (3) of the pump, a supporting cylindrical bush (6), an outer sleeve (7) with a two-diameters inner 20 bore, a compression coil spring (9) mounted around said central cylindrical body (4), and a guided inverted cup slider (10) with depression and grip radial extensions (11).

2- A system according to claim 1, characterized in that 25 the central tubular body (4) which is fitted on the protruding portion of the pump delivery tube (3) comprises the compression coil at the bottom a shoulder whereon said cylindrical spring (9) rests and around which supporting bush (6) is movably mounted, said bush having a 30 circular slotted groove serving as a seat for a resilient element (5) of the "Seeger" ring type, said ring (5) opposing the movement of the protruding inwardly and shoulder on the central body (4) during most of the actuating stroke of the slider (10). 35

3- A system according to claims 1 and 2, characterized in that the sleeve (7) having the two-diameters inner bore and slidably mounted around the supporting cylindrical

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- bush (6) is so sized as to keep said resilient element "Seeger" ring type (5), within the groove in said bush (6) in a compressed condition, and to release it only at the end of the actuating stroke of the slider (10).
- 4- A system according to the claims 1 to 3, characterized in that the slider (10) mounted around said components, including the compression coil spring (9), during its actuation stroke, loads said spring (9) and simultaneously moves downwards the sleeve (7) surrounding the supporting bush (6) and keeping said "Seeger" type resilient ring (5) in a compressed condition.
- 5- A system according to claims 1 to 4, characterized in that said outer sleeve (7) is provided at the bottom with resilient projections (8) or other suitable means tending to urge it upwards in the rest position.
- 6- A system according to the claims 1 to 5, characterized in that a sleeve (13) or any other member limiting the expansion stroke of the compression spring, and therefore of the slider, is mounted threadedly or similarly on the protruding upper portion of the central tubular body provided with the atomizing nozzle.
- 7- A system according to the claims 1 to 6, characterized in that a detail modification the head comprises a cylindrical tubular body (104) having at the bottom a collar with circular groove for accomodating the resilient ring member (105), a supporting bush (106) which can be locked on the neck of the container, an outer sleeve (107) slidable on said bush (106) replacing respectively the cylyndrical tubular body (4), the resilient member (5), the supporting bush (6) and the outer sleeve (7).
- 8- A system according to claims 1 to 7, characterized in that the cylindrical tubular body (104) is surrounded by a coil spring (109) which bears at the bottom on its collar and at the top against a shoulder on the slider, with the peculiarity that in the rest condition the cylindrical tubular body (104), through the resilient ring (105) housed in said accomodating groove and protruding therefrom, rests on the top plane of said bush (106) and, therefore, is

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prevented from moving down even if urged by the spring (109).

9- A system according to claims 1 to 8, characterized in that the outer sleeve (107) mounted around the supporting bush (106) on said head and provided at the top with a rim which protrudes inwards and is beveled, permits the resilient ring (105) to protrude in the rest position, but it makes it retract into its seat at the end of the actuation stroke or spring-loading stroke.

10- A system according to claims 1 to 9, characterized in that the outer sleeve (107) of the head, when its outer edge contacts the upper end of the supporting sleeve (106), is able to make the resilient ring (105) retract completely at the end of the actuation and loading stroke of the spring (109), thus eliminating the opposing force thereof and causing the self-release and snap-action of the spring (109).

11- A system according to claims 1 to 10, characterized in that in a detail modification in the head and more specifically in the inner side of the slider (110), the outer sleeve (107) which presses the resilient member (105) is replaced with a shaped annular ridge (207) integrally molded with the body of said modified slider (210).

12- A system according to claims 1 to 11, characterized in that it is realized on dispensing/atomizing heads of the single-use type wherein the container of the solution to be administered is constituted by a cylindrical cupshaped body (301) slidably mounted in the actuating slider (312) and containing the plunger of the pump, enclosed by a cylindrical housing (310) containing a coil spring (309) with a centering cup (304), a bush (306) with a seat for an annular resilient member (305) acting as a detent in the rest condition untill released by the larger diameter of the inner wall (307) of the housing (310), and capable of causing the self-release at the end of the spring-loading stroke, which at said moment snaps to cause a finely atomized dispensation.

13- A system according to claims 1 to 12, characterized

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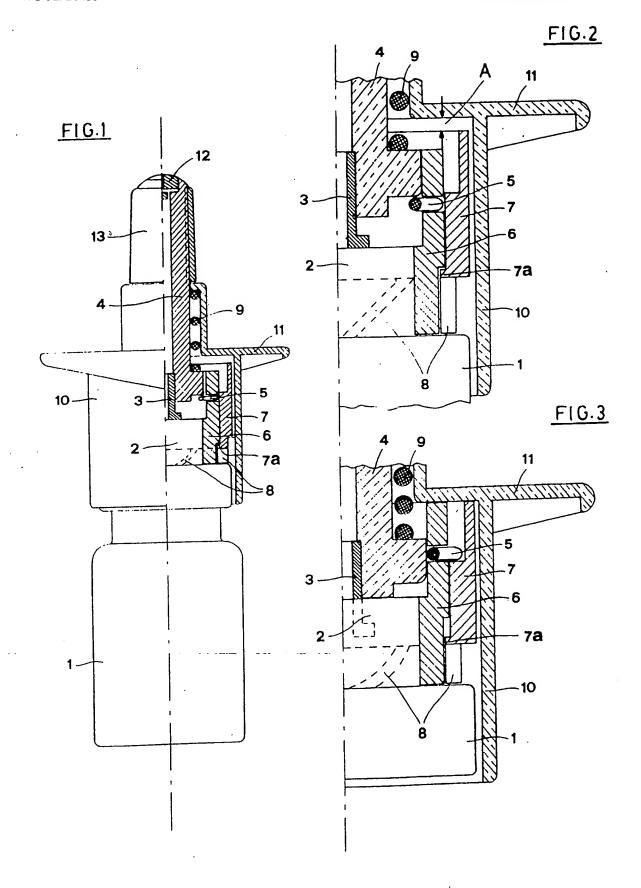
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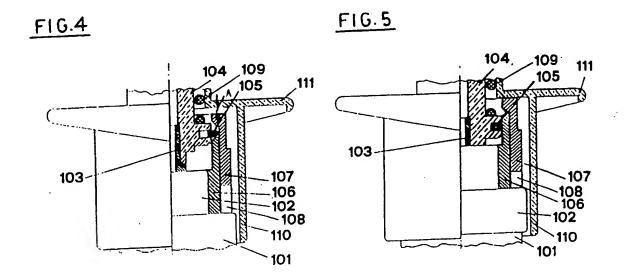
in that in a detail modification in the head and more specifically in the bush (6) or (306) with the seat for the annular resilient member (5) or (305), said bush (406) constructed with two ring segments (405) integrally molded in the thickness of the wall thereof, said segments being urged to the closed position by the engagement of their free ends (400), provided with a cam-like protrusion, against the sleeve (7) or the inner wall (307) of the cylindrical housing (310), or against the cylindrical tubular element (4) or the centering cup (304).

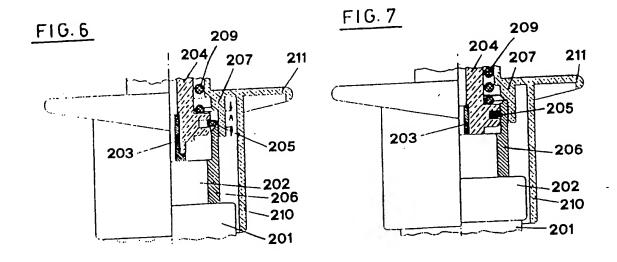
12, characterized system according to claim in that, in a detail modification, its head is provided interiorly, as a member for self-release of the loaded spring, with a shaped, resilient, slitted tubular member adapted to be having a conical end rim (505) (506) engaged by the edge (507) of the inner wall of the housing (510) of the assembly and compressed at the end of the spring-loading stroke so as to cease its detent function and cause the spring (509) to be snap-released.

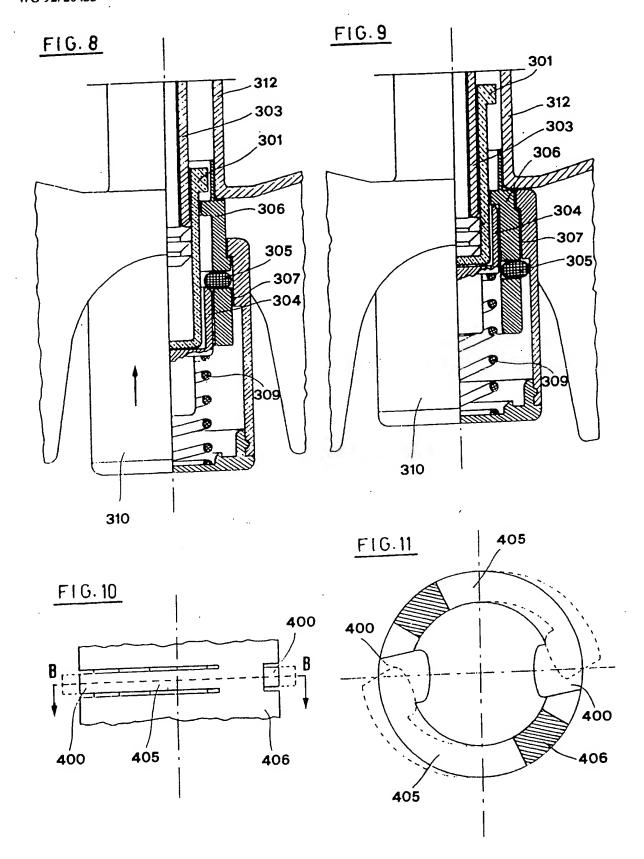
according to claims A system 15-20 characterized in that in a detail modification, said head is provided interiorly, as a member for self-release of the loaded spring, with a rigid bush (606) having an added resilient ring (605) operating similarly to the tubular resilient member (506) of he preceding claim.

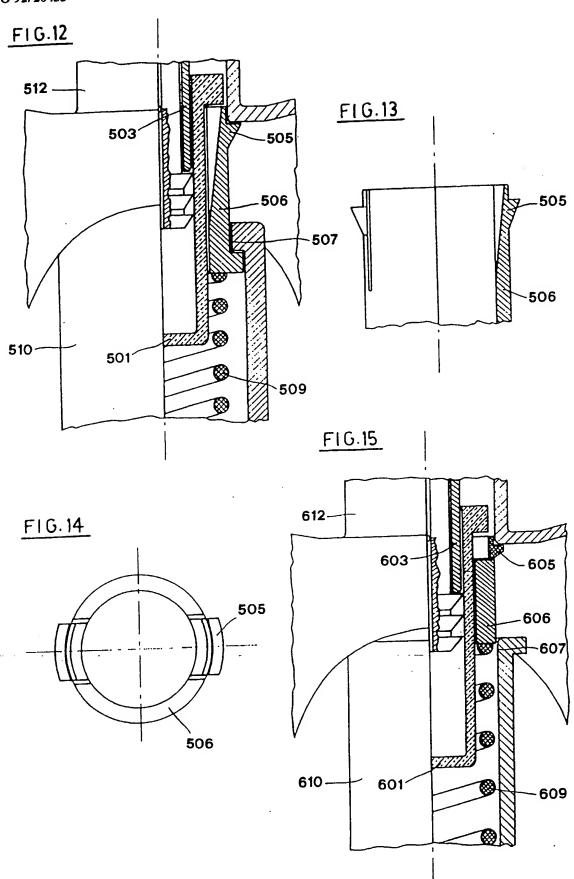
16- A system according to claims 1 to 15, characterized in that said dispensing and atomizing head has incorporated therein mechanical, self-actuation spring means pre-set for a first snap-release step, said release being effected with the aid of one or more resilient or mobile members used in opposition to other members, and said resilient or mobile members may be annular, tubular, ring-sector-shaped members or the like, always shaped suitably, all without excluding spheres or the like.











International Application No

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III. DOCU	MENTS CONSIDER	ED TO BE RELEVANT 9	of the relegant response 12	Relevant to Claim No.13			
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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. 17 59318

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This ansex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 04/09/92

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